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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/412,100 | 10/04/99 | WEI Z | 21829/31-(EB |

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | 11 |

DATE MAILED: 11/06/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Offic Action Summary | Applicati n No. 09/412,100 | Applicant(s) WEI ET AL. | |
|---|---|---|---|
| | Examiner Hope A. Robinson | Art Unit 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *10-29 and 39-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-9 and 30-38, SEQ ID NO: 23) in Paper No. 10 is acknowledged. Note that claim 9 will only be examined as it pertains to the elected sequence and applicant is reminded to cancel the non-elected subject matter.

2. The traversal is on the ground(s) that all groups of the invention are closely related and therefore, would require common areas of search and consideration, thus no benefit is derived from maintaining a restriction requirement.

Applicant's assertions that all groups are related and therefore would require common areas of search and consideration is not convincing. The nucleic acids of Group II are related to the protein of Group I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Moreover, Chapter 800 of the MPEP states that restriction practice is proper if the invention is shown to be independent (no disclosed relationship) or distinct (two or more subjects as disclosed are related). Thus, the restriction requirement is proper and final.

3. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

***Oath/Declaration***

4. The Oath/Declaration is objected to because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). It is noted that the alteration made the Oath/Declaration has been initialed, however, no date appears to signify when the alteration was made.

**Drawing**

5. The Drawings filed October 4, 1999 have been approved by the Draftsperson.

***Specification***

6. The specification is objected to because of the following informalities:

The specification is objected to because on page 6 the sequence identifier has extraneous periods see for example, "SEQ. ID. No. 21" which should be represented as "SEQ ID NO: 21", (see also the other sequences disclosed throughout the specification on pages 7+).

Correction is required.

### *Information Disclosure Statement*

7. The information disclosure statement filed on February 9, 2000 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement that are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: items 1-11, 13, 15-33, 35-105 and 108-163.

### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9 and 30-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to an isolated fragment of a hypersensitive response elicitor protein or polypeptide wherein said fragment does not elicit a hypersensitive response but has other activity in plants. The specification on page 4 discloses that

the present invention seeks to identify fragments of hypersensitive response elicitor proteins or polypeptides, which fragments do not elicit a hypersensitive response but are active when utilized in conjunction with plants. Furthermore, page 5 of the specification states that the "fragments of the claimed invention have other activity in plants" and there is no indicia as to what this "other activity" is.

In addition, the claims and the specification associate the claimed fragment as being represented by SEQ ID NO: 23 and 31. However, the instant disclosure of the protein or polypeptide fragment does not adequately describe the scope of the claimed genus. One or two members of the genus, is not a representative number of species to describe the genus.

In addition, the claims are directed to a method of using the isolated fragment to impart disease resistance, enhance plant growth and as an insect control, however, the claimed isolated fragment is not adequately described in the specification. Note that the specification does not provide any guidance for identification and utilization of other fragments of an *Erwinia* hypersensitive response elicitor protein or polypeptide wherein said fragments elicit a hypersensitive activity or any other activity, thus, it requires undue experimentation to practice the claimed invention. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as only two members of the claimed genus is disclosed. Thus, applicant was not in possession of the claimed genus.

In view of the foregoing, the disclosure lacks adequate written description as the claims are generically drawn to an isolated fragment of an *Erwinia* hypersensitive response elicitor

protein or polypeptide wherein said fragment does not elicit a hypersensitive response but has other activity in plants and the "activity" has not been described. Further, the specification fails to describe adequate representative species of the isolated fragment. Thus, for all these reasons, the specification lacks adequate written description and person skilled in the art would not be able to practice the claimed invention commensurate in scope with these claims without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-9 and 30-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto are indefinite because the claim recites that the fragment has "other activity" and there is no indication as to what is the "other activity".

Claims 4-7 and 9 are indefinite because the claims recite "SEQ. ID. No. 23" which is an improper format, as "SEQ ID NO: 23" is the proper format.

Claims 30-38 are indefinite because the methods recite "under conditions effective to impart disease resistance", "under conditions effective to enhance plant growth", and "under

conditions effective to control insects", however, the claims do not recite what conditions will produce these end results.

Claims 30, 33 and 36 are indefinite as the methods recite a "applying a fragment of hypersensitive response elicitor protein or polypeptide" and the methods do not recite a step as to how the protein is being applied. Does applicant intend "applying" to mean "administering" or "treating", if so the claims should be amended to clearly recite the intended meaning.

### *Claim Rejections - 35 U.S.C. § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-9 and 36-38 are rejected under 35 U.S.C. 102(a) as being anticipated by Zitter (WO 98/37752, September 3, 1998).

Zitter teach a method of controlling insects on plants which involves applying a hypersensitive response elicitor polypeptide or protein in a non-infectious form to a plant or plant

seed under conditions effective to control insects on the plant or plants produced from the plant seed (claims 36-38). The reference also teach that the polypeptide or protein is derived from *Erwinia, Pseudomonas and Xanthamonas, Erwinia amylovora, Pseudomonas syringae*, etc. and mixtures thereof. Zitter further teaches the sequence set forth in SEQ ID NO: 23 with a 100% sequence identity, (claims 1-9), see abstract and pages 1-5. Thus, the limitations of the claims are met by this reference.

11. Claims 1-9 and 30-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Wei et al. (WO 96/39802, December 19, 1996).

Wei teach a method of imparting pathogen resistance to plants comprising applying a hypersensitive response elicitor polypeptide or protein in a non-infectious form to a plant under conditions where the polypeptide or protein contacts the cells of the plant (claims 30-33). Wei also teach the sequence contained in SEQ ID NO: 23. Wei further teaches that the fragment is derived from *Erwinia pseudomonas*, *Xanthomonas* or *Phytophtora, Erwinia amylovora* and *Pseudomonas syringae* (claims 1-9). Therefore, the limitations of the claims are met by this reference (see abstract and pages 1-7 of reference).

12. Claims 1-3, 8 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Wei et al. (U.S. Patent No. 5,859,324, March 17, 1997).

The claimed invention is directed to an isolated fragment of a hypersensitive response elicitor protein or polypeptide, wherein said fragment does not elicit a hypersensitive response but has other activity in plants. Also the fragment is derived from *Erwinia pseudomonas*, *Xanthomonas* or *Phytophtora*, *Erwinia amylovora* and *Pseudomonas syringae*. Further, the claimed invention is directed to methods of imparting disease resistance to plants, enhancing plant growth and a method of insect control. Wei et al. teach a method of imparting pathogen resistance to plants which involves applying a hypersensitive response elicitor polypeptide or protein in a non-infectious form to a plant under conditions where the polypeptide or protein contacts cells of the plant (claims 30-32). We et al. Also teach the pathogens *Erwinia amylovora*, *Xanthomonas* and *Pseudomonas syringae* (see claims 1-3 and 8). Thus, the limitation of the claimed invention is met by this reference (see abstract and columns 1-8 and 17).

***The Basis For NonStatutory Douple Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-9 and 30-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 26-34 of copending Application No. 09/086,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are directed to an isolated fragment of a hypersensitive response elicitor protein or polypeptide derived from *Erwinia*, wherein said fragment consists of a C-terminal fragment of the amino acid sequence of SEQ ID NO: 23 or an N-terminal fragment of the amino acid sequence of SEQ ID NO: 23 and methods directed to controlling insects, enhancing growth and imparting disease resistance by applying the fragment. The copending application is directed to an isolated fragment of a hypersensitive response elicitor protein or polypeptide or full length *Erwinia*, wherein said fragment consists of a C-terminal fragment of the amino acid sequence of SEQ ID NO: 23 or an

N-terminal fragment of the amino acid sequence of SEQ ID NO: 23 and methods directed to controlling insects, enhancing growth and imparting disease resistance by applying the fragment. Although the scope of the claims in the two applications differ, the same protein is claimed with the same structure and characteristics. Therefore, the claims in both application are an obvious variation of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 36-38 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 22-27 of U.S. Patent No. 5,977,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method of insect control comprising applying a hypersensitive response elicitor polypeptide or protein wherein said applying includes treatment and the treated seeds are planted. Similarly the claimed invention is directed to a method of insect control which includes treatment of the plants during the applying of the protein and planting of the treated seeds. Therefore, the patented claims and the pending claims are an obvious variation of each other.

16. Claims 33-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 19-25 of U.S. Patent No. 6,277,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method of enhancing growth in plants comprising applying a hypersensitive response elicitor polypeptide or protein in a non-infectious form wherein said applying includes treatment and the treated seeds are planted. Similarly the claimed invention is directed to a method of insect control which includes treatment of the plants during the applying of the protein and planting of the treated seeds. Therefore, the patented claims and the pending claims are an obvious variation of each other.

17. Claims 30-32 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 19-23 of U.S. Patent No. 6,235,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method of imparting disease resistance to plants comprising applying a hypersensitive response elicitor polypeptide or protein wherein said applying includes treatment and the treated seeds are planted. Similarly the claimed invention is directed to a method of imparting disease resistance which includes treatment of the plants during the applying of the protein and planting of the treated seeds. Therefore, the patented claims and the pending claims are an obvious variation of each other.

***Conclusion***

18. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday and Wednesday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER